Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	William J. Hibbler	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 8182	DATE	10/31/2003
CASE TITLE	United States ex rel. Gross v. Aids Research Alliance - Chicago, et al.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

Defendants' Motion to Dismiss (doc. #)

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing [held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference [held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial [set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs [by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] . Enter memorandum opinion and order. For the attached reasons, Defendants' motion to dismiss is GRANTED.

(11) ■ [For further detail see order on the reverse side of the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.			
	Notices mailed by judge's staff.		NOV 03 2003 date docketed	36
	Notified counsel by telephone.			
✓	Docketing to mail notices.		docketing deputy initials	
✓	Mail AO 450 form.	U.S. DISTRICT COURT 03 OCT 31 PM 4:10	date mailed notice	
	Copy to judge/magistrate judge.			
JHC	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SANFORD M. GROSS,
Relator,

JOHN ASHCROFT, Attorney General of the United States, and PATRICK FITZGERALD, United States Attorney for the Northern District of Illinois
Plaintiffs,

v.

AIDS RESEARCH ALLIANCE-CHICAGO, et al,
Defendants.

No. 01 C 8182

The Honorable William J. Hibbler

MEMORANDUM OPINION AND ORDER

Sanford Gross initiated this action against the Defendants under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730 (FCA). Gross was a voluntary participant in a study sponsored by the National Institute of Health (NIH) to determine the effectiveness of a combination of medication on HIV patients. He alleges that the Aids Research Alliance-Chicago and participating physicians (who are also Defendants) made false or fraudulent claims to the NIH in order to receive funding. The Defendants move to dismiss Gross's complaint.

I. Factual Background

The NIH sponsors a research study to compare the impact of two doses of Subcutaneous Recombinant IL-2 (Proleukin®) on Viral Burden and CD4 + Cell Count in HIV-positive patients. AIDS Research Alliance is one of fifteen participating agencies in the study, and received approximately $3,700,000 in funding from the NIH to participate in the study. In October 1998, Dr.

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Thomas Klein, a doctor at AIDS Research Alliance and also a Defendant, invited Gross to be a patient in the study, and Gross began participating in the study beginning in December 1998.

According to Gross the study was grossly mismanaged. Participating doctors prescribed medication that was known to reduce the effectiveness of another drug used in the study. Doctors did not obtain informed consent. Doctors misplaced or lost patient files and study records. Doctors did not inform patients when their viral loads increased. In short, Gross alleges that the Defendants failed to monitor the study, maintain adequate records, and refrain from violating established standards of medical ethics. In addition, Gross alleged that the Defendants' various failures were reckless and/or intentional.

Gross also complains that numerous federal regulations required the Defendants to monitor the administration of the study, maintain adequate records, and refrain from scientific misconduct. He argues that the Defendants certified their compliance with the applicable regulations and that the NIH would not have funded the study had it known that Defendants would not comply (and were not complying) with the regulations. Thus, according to Gross, Defendants' failure to comply with the regulations coupled with their certification of compliance amounts to a false claim.

The FCA imposes liability on parties who "knowingly present[]" to the United States government or an agency thereof "a false or fraudulent claim for payment." 31 U.S.C. §3729(a). A cause of action brought under the FCA has three elements: (1) the defendant made a record or statement to get the government to pay money; (2) the record or statement was false or fraudulent; and (3) the defendant knew that the record or statement it submitted was false or fraudulent. *See United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999); *see also* 31 U.S.C. §3729(a)(2). Plaintiffs must plead FCA claims according to the heightened standards of

Federal Rule of Civil Procedure 9(b) and state the alleged fraud with particularity. *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003). In order to meet the requirements of Rule 9(b), a plaintiff must plead the "who, what, when and where of the fraud." *Id.* In other words, a plaintiff must plead the "identity of the person making the misrepresentation, the time, place and content of the misrepresentation and the method by which the misrepresentation was communicated." *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 923 (7th Cir.1992).

Defendants argue that Gross's pleadings fail to meet the level of specificity required under Rule 9(b) to state an FCA claim. The Court agrees. The Amended Complaint contains several paragraphs that refer generally to regulations with which Gross believes the Defendants failed to comply and to forms that Defendants were required, but failed, to submit to the government to maintain their funding. But Gross fails to allege any specific facts. Nowhere in the complaint does Gross specify which forms the Defendants falsely submitted, which Defendants falsely submitted the forms, on what dates the Defendants submitted these forms, or the amount of the Defendants' false claims. Instead, Gross offers only conclusory allegations that Defendants "knowingly" failed to submit required forms "for the purpose of justifying receipt of federal funds already received and to induce payment of additional federal funds." *See* Am. Compl., ¶¶ 102, 105, 108, 111, 114, 117, 120. Gross's conclusory allegations regarding the Defendants' failure to complete certain forms required to obtain federal funding fail to meet the heightened pleading standards of Rule 9(b). *See Garst*, 328 F.3d at 377; *United States ex rel. Garst v. Lockheed-Martin Corp.*, 158 F. Supp. 2d 816, 821 (N.D. Ill. 2001); *United States ex rel. Obert-Hong v. Advocate Health Care*, No. 99 C 5806, 2001 WL 303692, *2 (N.D. Ill. Mar. 28, 2001); *United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301, 1312 (11th Cir.2002).

Gross attempts to save his deficient pleading by arguing that he has pleaded sufficient facts to demonstrate that the Defendants submitted a false certification of compliance with NIH funding regulations in order to induce the NIH to provide funding for the Defendants' study. According to Gross, when the Defendants signed the grant application form they indicated their intent to comply with the laws, regulations, and policies to which a grant is subject," and therefore any failure to comply with these terms to which the grant is subject form the basis of a false claim. It is true that a knowingly false certification of compliance can create a cause of action under the FCA if the certification is a prerequisite to obtaining payment from the United States government. *United States ex rel. Siewick v. Jamieson Sci. and Eng'g, Inc.*, 214 F.3d 1372,1376 (D.C.Cir.2000); *see also Mikes v. Straus*, 274 F.3d 687, 698-700 (2d Cir.2001). But even if it is also true that compliance with various regulations was a prerequisite to obtaining the NIH funding for this study (a question the Court need not answer), it does not follow that simply because the Defendants did not strictly comply with the regulations that they submitted a false claim. Only statements that are materially false when made can be fraudulent. *See Murray v. ABT Assoc.*, 18 F.3d 1376, 1379 (7th Cir. 1999). There can be no "fraud in hindsight," *Denny v. Barber*, 576 F.2d 465, 470 (2d Cir. 1978), and innocent mistakes and negligence are not actionable, *Lamers*, 168 F.3d at 1018-19; *Hindo v. University of Health Sci./The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995). In other words, unless the Defendants intended, at the time of certification, that they would not keep their promise to comply with applicable regulations, there is no fraud. *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir.1999).

Gross alleges that the Defendants failed to properly monitor and document the study and, in some cases, prescribed medicine that they should not have prescribed or failed to obtain informed

consent. Gross further alleges that these failures caused Defendants to be in violation of many regulations with which they were required to comply. Of course on a motion to dismiss, the Court must accept these allegations as true. But again, Gross never details precisely what these failures were. What drugs were prescribed that should not have been? Which doctor failed to obtain his consent? On what date? Gross has pleaded, only generally, that the Defendants' methodology could have been improved. He must do more than simply plead that Defendants were not in compliance with all applicable regulations. He must plead sufficient facts demonstrate that the Defendants intended to deceive the United States. *See, e.g., Luckey*, 183 F.3d at 733 (observing that technical violations of a federal regulation on which a claim is based to not make the claim "false"); *Lamers*, 168 F.3d at 1019 (same); *Clausen*, 290 F.3d at 1311 (FCA does not create liability for health care providers merely for disregard of government regulations or improper internal policies, unless the provider knowingly asks the government to pay amounts it does not owe).

It is well settled that the FCA is a fraud prevention statute, not a means to ensure regulatory compliance, *Lamers*, 168 F.3d at 1020, and as noted earlier, mere negligence will not support a FCA claim. Where plaintiffs rely on technical violations to support a false certification FCA claim, the Seventh Circuit has required them to demonstrate some motive for the alleged deception. *See Lamers*, 168 F.3d at 1019. Thus, Gross must point to specific facts that indicate that, at the time Defendants certified their compliance, they had no intention of complying with the applicable regulations or at the very least that they had a motive not to comply with the regulations. He has not. Instead, Gross pleads only that "Defendants . . . have knowingly made false or fraudulent claims and certifications to justify retention of federal funds . . . and to induce payment of additional federal funds." Gross offers no facts to demonstrate that Defendants' failures to comply with the applicable

regulations were anything other than ordinary negligence and his conclusory allegation that Defendants knowingly certified compliance is insufficient to meet the pleading requirements imposed by Rule 9(b). Gross's FCA claims against the individual Defendants fail and the Defendants' motion to dismiss is GRANTED.

Gross also offers a final claim that Defendants conspired to submit a false claim. It too fails because he has failed to plead it with particularity. A conspiracy to submit a false claim necessarily involves a claim of fraud and thus is subject to the same pleading standards under Federal Rule of Civil Procedure 9(b) that govern fraud claims. In other words, the plaintiff is required to provide the "who, what, when and where" of an agreement to defraud the United States. *Ackerman v. Northwestern Mutual Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999). The Amended Complaint offers no facts to demonstrate the time, means or any other particulars involving the alleged conspiracy. The Defendants' motion to dismiss Relator's conspiracy claim is also GRANTED.

IT IS SO ORDERED.

10/31/03
Dated

Wm. J. Hibbler
The Honorable William J. Hibbler
United States District Court